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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,597	10/04/2001	Odile Cohen-Haguenaucr	8076.110USC2	2710

7590

02/26/2003

Attention: Katherine M. Kowalchuk
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EXAMINER

NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 02/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/970,597

Applicant(s)
Coheh-Haguenauer

Examiner
Dave Nguyen

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1632



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-46 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 27-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 27-33, 38, 39, 42-44, drawn to a Friend Murine Leukemia Virus based retroviral vector comprising an unmodified 3' Long terminal repeat, classifiable in Class 435, subclasses 91.4, 320.1 and 325.

Group II. Claims 34-37, 39, 42-46, drawn to a Friend Murine Leukemia Virus FB29 based retroviral vector deficient in a functional envelope protein of Friend Murine Leukemia Virus FB29, and/or to a Friend Murine Leukemia Virus based retroviral vector comprising a modified 3' Long terminal repeat, wherein the 3' Long terminal repeat has a deletion of the nucleotide sequences encoding viral promoter and enhancer sequence, and wherein the 3' Long terminal repeat has the nucleotide sequence of the restriction fragment as recited in claims 34, 35, 45, or 46, classifiable in Class 435, subclasses 91.4, 320.1 and 325.

The inventions are distinct, each from the other because of the following reasons:

The retroviral vector of Group I and the retroviral vector of Group II comprise materially distinct product and generate different functions and effects, and each of which is not required for use with each other, and generates distinct biological functions and effect. A search of Group I claims does not necessarily overlap with that of the group II claims, particularly since a modified 3' Long terminal repeat Friend Murine Leukemia Virus as recited in Group II claims is the essential feature of the claimed subject matter being sought in the claims, and is not particularly claimed in group I claims. Group I claims are essentially directed to any Friend Murine Leukemia Virus based retroviral vector comprising an unmodified 3' Long terminal repeat, which can be used as an expression vector to deliver and express an exogenous gene. As a result, a search for prior art and consideration of patentability does not necessarily overlap with one another. Thus, the inventions of Groups I and II comprise materially steps, and generate different functions and effects.

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Should Group I be elected, the claims of the elected Group are generic to a plurality of disclosed patentably distinct species comprising:

1/ A specifically named exogenous nucleotide sequence as recited in claim 30.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species as listed above even though this requirement is traversed.

2/ A specifically named exogenous promoter as recited in claim 32.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as listed above even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, and/or because of the patentably distinct species as listed above, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently

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named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen

A handwritten signature in black ink, appearing to be 'Dave Nguyen', with a long, sweeping line extending upwards and to the right.

**DAVE T. NGUYEN
PRIMARY EXAMINER**